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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,326	01/17/2002	Satoru Kuhara	JG-YY-4946D/500569.20085	4047

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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,326

Applicant(s)

KUHARA ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/499,717.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on April 2, 2003 has been entered. The claims pending in this application are claims 14-25. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the amendment.

Claim Objections

2. Claim 14 is objected to because of the following informality: the phrase "exposing to radiation the carrier" should be "exposing the carrier to radiation".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 14-18 and 21-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Rehman *et al.*, (Nucleic Acids Research, 27, 649-655, January 1999).

Regarding claims 14-18 and 22-24, Rehman *et al.*, teach immobilization of acrylamide-modified oligonucleotides on a carrier by co-polymerization. Aliquots of gel solution (0.2 µl) containing 75% glycerol, 10% total acrylamide (29:1 w/w acrylamide:bis-acrylamide), 5

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μ M 5' acryl-amide oligonucleotide, 0.125% w/v APS and 0.125% v/v TEMED were manually pipetted onto silanized glass microscope slides (acrylic silane-treated slides; CEL Associates, Houston, TX). Spotted slides were placed in a humid nitrogen atmosphere at room temperature for 5 min to allow polymerization. Polymerized slide arrays were subjected to electrophoresis in an agarose minigel box (50 mM Tris-acetate, pH 7.8, 2 mM EDTA, 20 V/cm, 20 min) to remove non-immobilized probe. Slides were rinsed in TE buffer or water and dried with a stream of nitrogen as recited in claims 16 (see right column in page 650 and pages 653 and 654, and Figure 6). Hybridization of the slide was performed in the presence of fluorescence labeled asymmetric PCR product (see page 651, left column). Note that: (1) the gel solution containing acrylamide (29:1 w/w acrylamide:bis-acrylamide), APS and TEMED is considered to contain a hydrophilic polymer (polyacrylamide) as recited in claim 14 since APS and TEMED in the gel solution gradually enhanced acrylamide:bis-acrylamide polymerization to form polyacrylamide as recited in claim 24 (containing at least some of polyacrylamide in the gel solution before complete polymerization); (2) hybridization of the slide to fluorescence labeled asymmetric PCR product is considered to be exposed the carrier to radiation because fluorescence is a visible light which is one kind of radiation (see attachment); (3) since co-polymerization attachment is specific for the terminal acrylamide group of the oligonucleotides (see abstract in page 649, right column in page 651, and Figure 1), acrylamide-modified oligonucleotides is considered to be indirectly fixed to the slide at its one end portion (5' terminus) as recited in claim 15; (4) silanized glass microscope slide is considered as a glass sheet as recited in claims 17 and 18; and (5) polyacrylamide is

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considered as a nonionic hydrophilic polymer as recited in claim 22 (see the specification, page 8, second paragraph) and a cellulose derivative as recited in claim 23 (containing carbon atoms).

Regarding claim 21, 5' -amino oligonucleotide was used in the method recited in claim 1 (see right column in page 651).

Regarding claim 25, as shown above, APS and TEMED in the gel solution gradually enhanced acrylamide:bis-acrylamide polymerization to form polyacrylamide. Since polyacrylamide is a polymer of acrylamide and initial concentration of polyacrylamide is zero, although one having ordinary skill in the art at the time the invention was made does not know exact concentration of polyacrylamide in the gel solution at each time point before gel complete polymerization, 0.1 to 2% polyacrylamide in the gel solution is reached at some point during the process of gel polymerization. Therefore, in the absence of convincing evidence to the contrary, the limitation as recited in claim 25 is considered to be inherent to the reference taught by Rehman *et al.*.

Therefore, Rehman *et al.*, teach all limitations recited in claims 14-18 and 21-25.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rehman *et al.*, (January 1999) as applied to claims 14-18 and 21-25 above, and further in view of Brown *et al.*, (US Patent No. 5,807,522, published on September 15, 1998).

The teachings of Rehman *et al.*, have been summarized previously, *supra*.

Rehman *et al.*, does not disclose to spot nucleic acids onto a glass sheet (slide) pretreated with poly-L-lysine as recited in claim 19.

Brown *et al.*, do teach to spot nucleic acids onto a glass sheet pretreated with poly-L-lysine (see columns 16-18).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have spotted nucleic acids onto a glass sheet pretreated with poly-L-lysine in view of the prior art of Rehman *et al.*, and Brown *et al.*. One having ordinary skill in the art would have been motivated to do so because: (1) immobilization of nucleic acids onto a glass sheet pretreated with poly-L-lysine was known in the art at the time the invention was made and the use of a solid support with a layer of

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positive charges would enhance efficiency of the immobilization of nucleic acid (with negative charges) on the sold support; and (2) the simple replacement of one kind of solid support (i.e., glass slides without poly-L-lysine) from another kind of solid support (i.e., glass slides pretreated with poly-L-lysine) in a method of fixing nucleic acid to a solid carrier would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rehman *et al.*, (January 1999) as applied to claims 14-18 and 21-25 above, and further in view of Shi *et al.*, (US Patent No. 5,919,626, published on July 6, 1999).

The teachings of Rehman *et al.*, have been summarized previously, *supra*.

Rehman *et al.*, do not disclose to spot nucleic acids onto a glass sheet (slide) pretreated with a silane coupling agent having an epoxy group as recited in claim 20.

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Shi *et al.*, do teach to spot nucleic acids onto a glass sheet pretreated with a silane coupling agent having an epoxy group (see columns 8, 14, 15, and 22).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have spotted nucleic acids onto a glass sheet pretreated with a silane coupling agent having an epoxy group in view of the prior art of Rehman *et al.*, and Shi *et al.*. One having ordinary skill in the art would have been motivated to do so because immobilization of nucleic acids onto a glass sheet pretreated with a silane coupling agent having an epoxy group was known in the art at the time the invention was made and the simple replacement of one kind of solid support (i.e., acrylic silane-treated glass slides) from another kind of solid support (i.e., glass slides pretreated with a silane coupling agent having an epoxy group) in a method of fixing nucleic acid to a solid carrier would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

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Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. No claim is allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
June 2, 2003



ETHAN WHISENANT
PRIMARY EXAMINER